

NUCLEAR REGULATORY COMMISSION

[NRC-2011-XXXX]

INCORPORATION OF RISK MANAGEMENT CONCEPTS IN REGULATORY PROGRAMS

AGENCY: Nuclear Regulatory Commission

ACTION: Request for public comments.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering development of a strategic vision to better incorporate risk management concepts into its regulatory programs. To continue NRC's longstanding goal to move toward more risk-informed, performance-based approaches in its regulatory programs, Chairman Gregory Jaczko has chartered a task force headed by Commissioner George Apostolakis to develop a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach that would continue to ensure the safe and secure use of nuclear material. As part of this initiative, the task force is seeking comments from external stakeholders on a series of questions that will provide input for the task force to consider in its work.

DATES: Submit comments by **[INSERT DATE: 45 days from the date of publication in the *Federal Register*]**. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Please include Docket ID **NRC-2011-XXXX** in the subject line of your comments. For additional instructions on submitting comments and instructions on accessing documents related to this action, see "Submitting Comments and Accessing Information" in the **SUPPLEMENTARY INFORMATION** section of this document. You may submit comments by any one of the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for documents filed under Docket ID **NRC-2011-XXXX**. Address questions about NRC dockets to Carol Gallagher, telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov.
- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.
- **Fax comments to:** RADB at 301-492-3446.

FOR FURTHER INFORMATION CONTACT: Christiana Lui, Office of Commissioner Apostolakis, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555-0001; telephone: 301-415-1801, e-mail: Christiana.Lui@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. SUBMITTING COMMENTS AND ACCESSING INFORMATION

Comments submitted in writing or in electronic form will be posted on the NRC Web site and on the Federal rulemaking Web site, <http://www.regulations.gov>. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed.

The NRC requests that any party soliciting or aggregating comments received from other persons for submission to the NRC inform those persons that the NRC will not edit their comments to remove any identifying or contact information, and therefore, they should not include any information in their comments that they do not want publicly disclosed.

You can access publicly available documents related to this document using the following methods:

- **NRC's Public Document Room (PDR):** The public may examine and have copied, for a fee, publicly available documents at the NRC's PDR, O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** Publicly available documents created or received at the NRC are available online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. From this page, the public can gain entry into ADAMS, which provides text and image files of the NRC's public documents. If you do not have access to ADAMS or if there are problems in accessing the documents located in ADAMS, contact the NRC's PDR reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdresource@nrc.gov. The FRN -Risk Management Survey is available electronically under ADAMS Accession Number ML112870118.
- **Federal Rulemaking Web Site:** Public comments and supporting materials related to this notice can be found at <http://www.regulations.gov> by searching on Docket ID **NRC-2011-XXXX**.

II. BACKGROUND

The NRC has a longstanding goal to move toward more risk-informed, performance-based approaches in its regulatory programs. In 1995, the Commission finalized and published its policy on how risk assessment would be used in agency decision making (see

<http://www.nrc.gov/reading-rm/doc-collections/commission/policy/60fr42622.pdf>). In the late 1990's-early 2000's time frame, the NRC staff undertook a number of initiatives to better incorporate risk insights and performance considerations into its regulatory programs. These initiatives resulted in fundamental changes to how the NRC conducts its licensing, inspection and rulemaking programs. The Commission has also directed the NRC staff to solicit input from industry and other stakeholders on performance-based initiatives, including areas that are not amenable to risk-informed approaches, to supplement the NRC's traditional deterministic system of licensing and oversight. It should be noted that deterministic¹ and prescriptive² regulatory requirements were based mostly on experience, testing programs and expert judgment, considering factors such as engineering margins and the principle of defense-in-depth. These requirements are viewed as being successful in establishing and maintaining adequate safety margins for NRC-licensed activities. The NRC has recognized that deterministic and prescriptive approaches can limit the flexibility of both the regulated industries and the NRC to respond to lessons learned from operating experience and support the adoption of improved designs or processes.

The NRC has as one of its primary safety goal strategies the use of sound science and state-of-the-art methods to establish, where appropriate, risk-informed and performance-based regulations. The NRC issued SECY-98-144, "White Paper on Risk-Informed and Performance-Based Regulation" (see

<http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1998/secy1998-144/1998-144scy.pdf>), to define the terminology and expectations for evaluating and implementing the

¹ A deterministic approach to regulation establishes requirements for engineering margin and for quality assurance in design, manufacture, and construction. In addition, it assumes that adverse conditions can exist and establishes a specific set of design basis events and related acceptance criteria for specific systems, structures, and components based on historical information, engineering judgment, and desired safety margins. An example is a defined load on a structure (e.g., from wind, seismic events, or pipe rupture) and an engineering analysis to show that the structure maintains its integrity.

² A prescriptive requirement specifies particular features, actions, or programmatic elements to be included in the design or process, as the means for achieving a desired objective. An example is a requirement for specific equipment (e.g., pumps, valves, heat exchangers) needed to accomplish a particular function (e.g., remove a defined heat load).

initiatives related to risk-informed, performance-based approaches. The paper defines a performance-based approach as follows:

“A performance-based regulatory approach is one that establishes performance and results as the primary basis for regulatory decision-making, and incorporates the following attributes:

- (1) measurable (or calculable) parameters (i.e., direct measurement of the physical parameter of interest or of related parameters that can be used to calculate the parameter of interest) exist to monitor system, including facility and licensee, performance,
- (2) objective criteria to assess performance are established based on risk insights, deterministic analyses and/or performance history,
- (3) licensees have flexibility to determine how to meet the established performance criteria in ways that will encourage and reward improved outcomes; and
- (4) a framework exists in which the failure to meet a performance criterion, while undesirable, will not in and of itself constitute or result in an immediate safety concern.³”

Performance-based approaches can be pursued either independently or in combination with risk-informed approaches. The NRC staff and the Commission continued to make progress on developing policies and guidance related to performance-based approaches and subsequently issued documents such as SECY-00-191, “High Level Guidelines for Performance-Based Activities” (see <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0191/2000-0191scy.pdf>); and NUREG/BR-0303, “Guidance for Performance-Based Regulation” (see <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0303/>).

Risk and performance considerations for materials and fuel cycle licensees were documented in SECY-99-062, “Nuclear Byproduct Material Risk Review” (see <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1999/secy1999-062/1999-062scy.pdf>); SECY-99-100, “Framework for Risk-Informed Regulation in the Office of Nuclear Material Safety and Safeguards” (see

[³ Using the previous example \(footnote 2\), a performance-based approach might provide additional flexibility to a licensee on plant equipment and configurations used to accomplish a safety function \(e.g., removing a heat load\), but the performance criteria could not be the actual loss of a safety function that would result in the release of radioactive materials.](http://www.nrc.gov/reading-rm/doc-collections/commission/secys/1999/secy1999-100/1999-</p></div><div data-bbox=)

[100scy.pdf](#)); SECY-00-0048, "Nuclear Byproduct Material Risk Review" (see <http://www.nrc.gov/reading-rm/doc-collections/commission/secys/2000/secy2000-0048/2000-0048scy.pdf>); and the Phase II Byproduct Material Review (ADAMS Accession No. ML0124303962).

Perhaps the most significant programmatic adoption of risk-informed and performance-based considerations in the reactor area took place with implementation of the Reactor Oversight Process (ROP) in April of 2000. The ROP replaced the previous Systematic Assessment of Licensee Performance (SALP) program with explicit consideration of risk and performance considerations. The normal "baseline" inspection program is focused on the more risk-important areas of plant operations. In addition, events or conditions at plants are assessed for significance using probabilistic risk models. The results of such assessments are used to direct additional oversight to plants with more significant findings. A more recent reactor initiative that adopts a risk-informed and performance-based approach is the incorporation of the National Fire Protection Association (NFPA) standard NFPA 805, "Performance-Based Standard for Fire Protection for Light-Water Reactor Electric Generating Plants" into NRC's regulations (*Federal Register*, 69 FR 33536; June 16, 2004; see <http://edocket.access.gpo.gov/2004/pdf/04-13522.pdf>). NFPA 805 provides deterministic requirements that are very similar to those in NRC's traditional fire protection regulations, and also includes performance-based methods for evaluating plant configurations that provide a comparable and equivalent level of safety intended by the conservative deterministic requirements. The performance-based methods allow engineering analyses to demonstrate that the changes in overall plant risk that result from these plant configurations is acceptably small and that fire protection defense-in-depth is maintained.⁴ Defense-in-depth as applied to

⁴ Building upon the guidance in Regulatory Guide 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Regulatory Guide 1.205, "Risk-Informed, Performance-Based Fire Protection for Existing Light-Water Nuclear Power Plants," states:

fire protection means that an appropriate balance is maintained between: (1) preventing fires from starting; (2) timely detection and extinguishing of fires that might occur; and (3) protection of SSCs important to safety from a fire that is not promptly extinguished. The adoption of NFPA 805 provides a licensee with flexibility regarding how to implement its fire protection program while maintaining an acceptable level of fire safety.

In the materials area, the NUREG-1556 series, Volumes 1-21, "Consolidated Guidance About Materials Licensees" (see <http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>) was developed in the late 1990's to pull together into one place the various guidance documents written over the years for the wide variety of materials licensees. These documents allow license applicants to find the applicable regulations, guidance and acceptance criteria used in granting a materials license. Operational experience (performance) and risk insights guided the development of these documents. Over time the guidance in NUREG-1556 has been revised to further incorporate risk insights, performance considerations and changing technology. A new revision to the series is under development to address security and other issues.

The materials inspection program was fundamentally revised in 2001---both in terms of approach and frequency--- in the Phase II Byproduct Material Review. The inspection approach was modified to emphasize licensee knowledge and performance of NRC-licensed activities over document review. Inspectors now review a licensee's program against focus areas that reflect those attributes which are considered to be most risk-significant. If a licensee's performance against a given focus element during the inspection is considered to be acceptable, the inspector moves on to the next focus element. Performance concerns or questions lead an inspector to go deeper into that area. In addition, inspection frequencies

Prior NRC review and approval is not required for individual changes that result in a risk increase less than 1×10^{-7} /year (yr) for CDF [core damage frequency] and less than 1×10^{-8} /yr for LERF [large early release frequency]. The proposed change must also be consistent with the defense-in-depth philosophy and must maintain sufficient safety margins. The change may be implemented following completion of the plant change evaluation.

were revised based on risk insights from the NUREG/CR-6642 effort as well as licensee performance over time.

III. WHY RISK MANAGEMENT AND WHY NOW?

The initiatives identified above have been successful in making the NRC's regulatory programs less deterministic and prescriptive and more risk-informed and performance-based. The risk-informed approach has provided the NRC the ability to make regulatory decision making more systematic, more objective, more consistent, and more transparent. In addition, it has allowed the NRC to better focus its licensing and inspection efforts on the most risk-significant areas and has provided flexibility in addressing technological change, thus increasing effectiveness and efficiency. However, current projections for flat or declining budgets for the foreseeable future may necessitate NRC to adjust the way it does business to continue to fulfill its mission.

Accordingly, a task force headed by Commissioner George Apostolakis is developing a strategic vision and options for adopting a more comprehensive and holistic risk-informed, performance-based regulatory approach for reactors, materials, waste, fuel cycle, and transportation that would continue to ensure the safe and secure use of nuclear material (ADAMS Accession No. ML110680621). The task force was afforded the flexibility to provide options ranging from a complement to or alternative to the existing regulatory framework. The task force is expected to complete its work by May 2012.

One of the approaches being considered by the task force is risk management. Risk management is being widely used in various sectors, including government agencies, financial institutions and technology companies, to address the kinds of challenges the NRC faces and that the task force must address. In a 2008 report, the Government Accountability Office (GAO) stated that:

Using principles of risk management can help policymakers reach informed decisions regarding the best ways to prioritize investments in security programs so that these investments target the areas of greatest need. Broadly defined, risk management is a strategic process for helping policymakers make decisions about assessing risk, allocating finite resources, and taking actions under conditions of uncertainty.

While the GAO report was focused on homeland security issues, the task force believes that risk management concepts may represent a logical evolution from the risk-informed, performance-based philosophy that has governed many NRC regulatory activities for more than a decade and may be particularly effective in addressing the challenges that the NRC faces in the years to come. Risk management concepts and approaches vary, but generally include the following:

- Identification and framing of the issue
- Identification of options
- Analysis
- Deliberation for integrated decision making
- Implementation
- Performance monitoring and feedback.

Risk management allows for various approaches to consideration of risk in decision making, including both quantitative and qualitative tools, which is essential in the broad range of NRC regulatory programs. It may also provide program managers with a more systematic approach to resource allocation, whether in budget formulation, response to events or licensing decisions.

IV. THE ROLE OF STAKEHOLDER INPUT

This effort could not be successful without meaningful stakeholder input. The task force is soliciting the views of both internal and external stakeholders to assist them in developing sound and effective long-term strategies. The process of interaction with internal stakeholders is ongoing. However, this *Federal Register* notice is intended to solicit the views of external stakeholders on the options and specific actions that the NRC might undertake in moving toward a more comprehensive and holistic risk management approach for its regulatory programs.

The task force is seeking stakeholder input on the following questions to assist in its work. The task force will use the comments received to inform its deliberations, and its report will address the key issues raised in the comments which are relevant to task force activities. However, the task force does not plan to prepare a detailed response to individual comments or prepare an analysis of comments.

1. Do you believe there is a common understanding and usage of the terms risk-informed, performance-based, and defense-in-depth within the NRC, industry, and other stakeholders? Which terms are especially unclear?
2. What are the relevant lessons learned from the previous successful and unsuccessful risk-informed and performance-based initiatives?
3. What are the relevant lessons learned from the previous successful and unsuccessful deterministic regulatory actions?

4. What are the key characteristics for a holistic risk management regulatory structure for reactors, materials, waste, fuel cycle, and security?
5. Should the traditional deterministic approaches be integrated into a risk management regulatory structure? If so, how?
6. What are the challenges in accomplishing the goal of a holistic risk management regulatory structure? How could these challenges be overcome?
7. What is a reasonable time period for a transition to a risk management regulatory structure?
8. From your perspective, what particular areas or issues might benefit the most by transitioning to a risk management regulatory approach?

The task force requests comments on these questions by [INSERT DATE: 45 days from publication in *the Federal Register*] to assist in its efforts.

Dated at Rockville, Maryland, this ____ day of _____, 2011.

For the Nuclear Regulatory Commission.

Christiana Lui,
Office of Commissioner Apostolakis.